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(54) **Differential diagnosis for mycobacterial and pseudomonas species using species-specific upstream p34 gene region probes**

(57) The present invention relates to methods and devices for detecting and differentiating between Mycobacterium strains in a sample based upon species-specific upstream p34 gene region (us-p34) sequences. New us-p34 sequences and probes and primers derived therefrom are provided as well as methods and diagnostic kits based on the same. The invention also relates

to methods and devices for detecting and differentiating between Pseudomonas strains in a sample based upon species-specific rRNA opreon (*rrn*) sequences. New *rrn* sequences and probes and primers derived therefrom are provided as well as methods and diagnostic kits based on the same.

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EUROPEAN SEARCH REPORT

Application Number
EP 02 44 7026

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	COETSIER CHRISTOPHE ET AL: "Duplex PCR for differential identification of Mycobacterium bovis, M. avium, and M. avium subsp. paratuberculosis in formalin-fixed paraffin-embedded tissues from cattle." JOURNAL OF CLINICAL MICROBIOLOGY, vol. 38, no. 8, August 2000 (2000-08), pages 3048-3054, XP002172497 ISSN: 0095-1137 * page 3051 - page 3053; figures 1,2; tables 1,2 *	1-28	C12Q1/68
X	VANNUFFEL P ET AL: "P34 and F57 based-multiplex PCR assay for discrimination between tuberculous and nontuberculous mycobacteria." ABSTRACTS OF THE INTERSCIENCE CONFERENCE ON ANTIMICROBIAL AGENTS AND, vol. 38, 1998, page 158 XP001010524 38th Interscience Conference on Antimicrobial Agents and Chemotherapy; San Diego, California, USA; September 24-27, 1998, 1998 * the whole document *	1-28	TECHNICAL FIELDS SEARCHED (Int.Cl.7) C12Q
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
THE HAGUE		1 July 2002	Gabriels, J
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-28 (partially)



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**LACK OF UNITY OF INVENTION
SHEET B**

Application Number

EP 02 44 7026

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-28 (partially)

Invention 1:

A non-tuberculosis Mycobacterium species-specific upstream p34 gene region (us-p34) nucleotide primer/probe, fragments thereof, its complement, probes specifically hybridising to these sequences, the corresponding sequence wherein T has been replaced by U, Compositions containing these, diagnostic kits, solid supports, and micro-arrays thereof for detecting and/or identifying (differential detection) a non-tuberculosis Mycobacterium strain or for identifying new upstream p34 gene region sequences.

2. Claims: 1-28 (partially)

Invention 2 to 74:

A non-tuberculosis Mycobacterium species-specific upstream p34 gene region (us-p34) nucleotide primer/probe comprising SEQ ID NO:1, fragments thereof, its complement, probes specifically hybridising to this sequence, the corresponding sequence wherein T has been replaced by U, Compositions containing these, diagnostic kits, solid supports, and micro-arrays thereof for detecting and/or identifying (differential detection) a non-tuberculosis Mycobacterium strain, identifying new upstream p34 gene region sequences.

Idem for invention 3 to 68 but limited to the sequences having SEQ ID NOs 2-74. (SEQ ID NO:2 represents invention number 3,...,SEQ ID NO:62 represents invention number 63,..., and SEQ ID NO:74 represents invention number 75)